Registration Decision RD2010-02

RootShield Biological Fungicide, *Trichoderma harzianum* Rifai strain KRL-AG2

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Registration Decision for *Trichoderma harzianum* Rifai strain KRL-AG2

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Pest Control Products Regulations, is granting full registration for the sale and use of RootShield Technical Biological Fungicide, RootShield HC-Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide containing the technical grade active ingredient *Trichoderma harzianum* Rifai strain KRL-AG2, to control a variety of fungal diseases on greenhouse peppers, greenhouse and field tomato and strawberry, field lettuce, outdoor nursery plants and bean, pea, lima bean, lentil and soybean seeds.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision *PRD2009-13, RootShield Biological Fungicide, Trichoderma harzianum Rifai strain KRL-AG2.* This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Trichoderma harzianum* Rifai strain KRL-AG2 and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2009-13. This decision is consistent with the proposed registration decision stated in PRD2009-13.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-13, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

What Is *Trichoderma harzianum* Rifai strain KRL-AG2?

Trichoderma harzianum Rifai strain KRL-AG2 is a fungus that protects plants from disease-causing fungal pathogens by secreting cell degrading enzymes and antibiotics and by invading and growing within pathogenic fungi to suppress their growth.

The end-use products, RootShield HC-Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide are commercial fungicide products that contain *T. harzianum* Rifai strain KRL-AG2 as the active ingredient. These products control fungal root disease in soils and foliar disease in ornamental and food crops.

Health Considerations

Can Approved Uses of *Trichoderma harzianum* Rifai strain KRL-AG2 Affect Human Health?

***Trichoderma harzianum* Rifai strain KRL-AG2 is unlikely to affect your health when RootShield Biological Fungicide is used according to the label directions.**

People could be exposed to *T. harzianum* Rifai strain KRL-AG2 when handling and applying the products. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic byproducts), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses for the purpose of identifying any potential pathogenicity, infectivity and toxicity concerns. When *T. harzianum* Rifai strain KRL-AG2 was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* (*FDA*) prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the *Pest Control Products Act* (*PCPA).* Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Strains of *T. harzianum* are common in nature and the use of RootShield Biological Fungicide products to control fungal diseases in crops is not expected to significantly increase natural environmental background levels of this microorganism. Furthermore, when *T. harzianum* Rifai strain KRL-AG2 was administered orally to rats, no signs that it caused toxicity or disease were observed. Secondary metabolites of toxicological significance (i.e., peptaibols) have been shown to be produced by certain naturally occurring strains of *T. harzianum* (including strain KRL-AG2). However, the use of RootShield Biological Fungicide products is not expected to result in a sustained increase in levels of these peptaibols beyond the naturally occurring background levels of those produced by native *T. harzianum* strains. These metabolites are expected to be short lived in the environment once produced, as they are susceptible to ultraviolet light, high temperatures and various microbial processes in the environment.

The establishment of a MRL is not therefore required for *T. harzianum* Rifai strain KRL-AG2. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risks are minimal to non-existent.

Occupational Risks From Handling RootShield HC-Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide

Occupational risks are not of concern when RootShield HC-Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide is used according to label directions, which include protective measures.

Workers using RootShield Fungicide products can come into direct contact with *T. harzianum* Rifai strain KRL-AG2 on the skin, in the eyes or by inhalation. For this reason, the label will specify that users exposed to RootShield Biological Fungicide products, must wear gloves, long-sleeved shirts, long pants, eye goggles and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator/mask with any N-95, R-95, P-95 or HE filter for biological products, and shoes plus socks.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Trichoderma harzianum* Rifai strain KRL-AG2 Is Introduced Into the Environment?

Environmental risks are not of concern.

Information on the environmental fate of *T. harzianum* Rifai strain KRL-AG2 suggests that, as a soil microorganism, it is likely that *T. harzianum* Rifai strain KRL-AG2 could survive in outdoor soil under suitable environmental conditions (i.e., type of soil, moisture, acidity levels, and temperature) but that over time the populations of *T. harzianum* Rifai strain KRL-AG2 should return to naturally occurring levels.

There are no published reports of disease associated with *T. harzianum* Rifai strain KRL-AG2 in birds, wild mammals, fish, insects, earthworms, plants, except for the intended pest. Furthermore, studies designed to examine the effects of *T. harzianum* to birds, wild mammals, terrestrial insects, earthworms and soil microorganisms reported no adverse effects.

Value Considerations

What Is the Value of RootShield HC-Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide?

RootShield HC-Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide contain a fungus that suppresses the following: (1) root diseases caused by *Pythium* spp., *Rhizoctonia* spp. and *Fusarium* spp. on greenhouse tomatoes, peppers and cucumbers as well as outdoor nursery crops, (2) grey mould in strawberries, (3) botrytis stem canker in tomato, (4) botrytis blight in lettuce and outdoor ornamentals, and (5) seed rot caused by *Pythium* spp., *Rhizoctonia* spp. and *Fusarium* spp. on beans, peas, lima beans and soybean.

RootShield Biological Fungicides contribute to the suppression and management of plant diseases that might otherwise require frequent application of fungicides for disease control. The use of RootShield Biological Fungicides will help reduce fungicide use in greenhouses and the field, with consequent reduction in occupational, dietary and environmental exposure.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of RootShield HC-Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposures to *T. harzianum* Rifai strain KRL-AG2, anyone handling, mixing/loading, applying or involved in clean-up/repair activities of RootShield Biological Fungicides (wettable powder or granular formulation), must wear waterproof gloves, a long-sleeved shirt, long pants, eye goggles and a dust/mist filtering respirator mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator mask with any N-95, R-95, P-95 or HE filter for biological products, and shoes plus socks. Furthermore, early-entry workers are restricted from entering areas where RootShield HC-Biological Fungicide Wettable Powder has been applied as a foliar spray for a period of four hours unless wearing the indicated personal protective equipment, with the exception of eye goggles and a dust/mist filtering respirator, which are required only until the spray mist has settled.

Environment

As a general precaution, label statements require handlers to not contaminate irrigation or drinking water or aquatic habitats. Instructions are also provided to limit runoff from fields treated with this product from entering lakes, streams, ponds or other water bodies. In addition, the label states that treated plant material must not be used as a substrate for mushrooms.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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5 As per subsection 35(1) of the *Pest Control Products Act.*

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

2.0 Human and Animal Health

3.0 Environment

4.0 Value

PMRA Document Number: 1308741
Reference: Part 10 - Value For A Plant Protection Product, Data Numbering Code: M10.0,M10.1,M10.2.2

PMRA Document Number: 1356327
Reference: Attachment 8-product Performance, Data Numbering Code: M10.2,M2.14

PMRA Document Number: 1356328
Reference: 1998, Evaluation Du Produit De Lutte Biologique Rootshield Contre Le Pythium Sur Culture De Tomate De Serre En Solutions Nutritives Et En Mousse De Tourbe. Data Numbering Code: M10.2.2

PMRA Document Number: 1356329
Reference: 1997, Disease Prevention In Greenhouse Tomato: An IPM Perspective. Attachment 9. Data Numbering Code: M10.2.2

PMRA Document Number: 1356335
Reference: Attachment 11-6. Integrated Flower Disease Management; 7. Major Greenhouse Flower Diseases, Data Numbering Code: M10.3.1,M2.14

PMRA Document Number: 1356336
Reference: Nature And Economics Of Disease Problem. Attachment 12, Data Numbering Code: M10.4.2

PMRA Document Number: 1356337
Reference: Current Crop Protection Tools. Attachment 13, Data Numbering Code: M10.4.3

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number: 1738535
Reference: Poirier, L., Quiniou, F., Ruiz N., Montagu, M., Amiard, J., and Pouchus Y. F. 2007. Toxicity Assessment of Peptaibols and Contaminated Sediments on *Crassostrea gigas* Embryos. Aquatic Toxicology 83:254B262. Data Numbering Code: M9.6